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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,171	01/17/2002	Kai-Uwe Lewandrowski	CSI 126	4535

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,171	LEWANDROWSKI, KAI-UWE	
	Examin r	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election **without** traverse of group I, claims 1-19, drawn to a method of detecting osteoporosis in Paper No. 5 is acknowledged. Claims 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of osteoporosis caused by bacterial infection, does not reasonably provide enablement for detecting osteoporosis by measuring concentration of other types of pathegens such as viruses, viral produced factors, protozoa, protozoal produced factors, parasites, parasitic produced factors, fungi, and fungal produced factors, as recited in instant claims 12, and 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The enablement test requires require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See MPEP § 2164.01, reciting In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). To determine whether there is sufficient evidence to

support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue", following factors are considered: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, at 737

In this case, the scope of the claims is broader than the disclosure in the specification since ; the efficacy of the invention is unpredictable because of the wide variety of pathogens known to a skilled artisan. No direction or guidance, or working example is given by the inventors with respect to the recited pathogens in claims 12 and 13. In this case, undue experimentation is required to test the efficacy of the claimed invention and the disclosure is not enabling the skilled artisan with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "a period of time" in claim 2 is vague and indefinite, as the metes and bounds of the scope of the claims are uncertain.

Claims 4-5 and 7-11 have improper dependency on claim 3. Claim 3 requires the bone related cell samples be obtained under conditions that HSP response is not induced, while the depending claims require HSPs.

Remaining claims are rejected as depending on the indefinite base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay (WO00/13024) in view of Nair (Calcif. Tissue Int., vol. 64, no. 3, Mar. 1999).

Findlay teaches the method of diagnosing osteroporosis or osteroarthritis by detecting biochemical markers. See p. 3, line 22 – p. 4. The invention includes method steps of taking bone sample and measure or estimate the level of the marker of bone remodeling in the sample by extracting mRNA from the sample, estimating the level of expression for the makers by measuing the quantity of mRNA specific for that marker, and comparing the level to a standard. While the reference teaches using markers associated with bone resorption, the reference fails to teach using the pathogens or heat shock proteins as required by the instant invention. See p. 4, line 16 – p. 5, line25.

Nair teaches that molecular chaperones (heat shock proteins) stimulate bone resorption. See abstract. The reference teaches that HSP 70 is capable of inducing osteolysis. See p. 217, second column, last par. P. 218, first column, last par.

Given the general teaching in Findley that the method of detection of osteoporosis by screening the concentration of markers associated with bone resorption, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Nair for specific types of markers that are also stimulate bone resorption.

2. Claims 1, 12-14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findley in view of Reddi et al. (J. Bone and Mineral Res., v. 13, no. 8, Aug. 1998) ("Reddi").

Findley, discussed above, fails to teach the specific markers used in the instant invention.

Reddi teaches that the E. coli chaperonin 60 (groEL) stimulates bone resorption and osteoclast formation. See abstract. The reference suggests that bacterial cpn60s may play a role in the osteolysis associated with bone infections. The reference teaches that Antinobacillus actinomycetemcomitans causes periodontal bone loss and contains a potent bone-resorbing protein which is also found in cpn60 of E. coli. See p. 1260, col. 2, abridging paragraph. The reference suggests the possibility that bacterial infection of the chaperonins could be responsible for bone infection diseases such as osteoporosis. See p.1265, col. 1, abriding paragraph.

Given the general teaching in Findley that the method of detection of osteoporosis by screening the concentration of markers associated with bone resorption, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Reddie for specific types of markers that are also stimulate bone resorption.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner

SREENI PADMANABHAN
PRIMARY EXAMINER 8/25/03